

REMARKS

The Office Action mailed December 16, 2004 has been received and reviewed. Claims 1 through 20 were pending in the application, while claims 13 through 15 were withdrawn from consideration. Claims 1 through 12 and 16 through 20 were rejected. The application is to be amended as previously set forth. Claims 9 and 19 are to be canceled without prejudice or disclaimer. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

A. Subsequent Species Elections:

Applicants hereby affirm their election, with traverse, to prosecute the species of infection with pathogenic bacteria. The basis for applicants' traversal is that applicants believe that a reasonable number of species were included in the application before the species election. Cf. 37 C.F.R. § 1.141.

B. 35 U.S.C. § 112:

Claims 1 through 12 and 16 through 20 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. First, it was thought that the recitation of a molecule comprising an [oligo]peptide, while the specification uses a molecule consisting of a specific peptide sequence as indicated in Table 6, was too broad. (Office Action, p. 3). Further, it was thought that treatment of anthrax was too unpredictable. (Id., at 4-5). Applicants have amended the claims, and partially in view of the amendments, traverse the rejection.

With respect to claims 1 and 2 and the claims dependent thereon, the claims are to be amended to recite that the molecule "consists of" the oligopeptide or functional analogue thereof, which should remove the first part of the rejection as it is understood.

With respect to the unpredictability of treating anthrax, applicants would respectfully point out that the references cited by the Office involve the administration of LeTx (Lethal) toxin, and not infection with the pathogen anthrax.

As described in the as-filed application at page 4, lines 5-20,

“However, the primary cell type affected in anthrax pathogenesis is the macrophage. LF has been shown to cleave short N-terminal fragments from mitogen or extracellular signal-regulated MAPKK-1, MAPKK-2, MAPKK-3, and MAPKK-6, the upstream activators of extracellular signal-regulated kinase 1 (ERK1), ERK2, and p38. Recent data show that this results in inhibiting release, but not production, of the pro-inflammatory mediators, NO and tumor necrosis factor-alpha (TNF-alpha). In addition, high levels of lethal toxin lead to lysis of macrophages within a few hours, by an unknown mechanism. Recent data suggests that this happens due to inhibition of growth-factor pathways leading to macrophage death. These observations suggest that at an early stage in infection, lethal toxin may reduce (or delay) the immune response, whereas at a late stage in infection, high titers of the bacterium in the bloodstream trigger macrophage lysis and the sudden release of high levels of NO and TNF-alpha. This may explain the symptoms before death which are characterized by the hyperstimulation of host macrophage inflammatory pathways, leading to dramatic hypotension and shock. These symptoms resemble those of LPS induced septic shock, whereby it is of note LPS-nonresponder mice such as C3H/HeJ are also quite resistant against anthrax toxin.”

(Emphasis added).

Taking this insight of anthrax pathogenesis into consideration, the inventors (as evidenced by the application as filed) believe that the two references cited by the Office relate to the unknown mechanism wherein the lethal toxin is held responsible for macrophage lysis, but not as much to the inflammatory condition caused by anthrax pathogen.

Applicants therefore are amending the independent claims to recite that the inflammatory conditions are those regulated by NFkappaB. Basis for this amendment is inherent throughout the application, but specific basis can be found at page 7, line 12 to page 8, line 30 and page 24, line 13 to page 26, line 14.

Unfortunately in this case, due to government regulations with respect to anthrax, applicants are unable to conduct experimentation involving anthrax infection, which research should support them in this regard.

With respect to claim 16 (which does not use the “molecule” or anthrax language), applicants have amended this claim to define that the oligopeptide (or functional analog thereof) administered therein is selected from Table 6.

In view of the foregoing, applicants respectfully request that the rejection be withdrawn.

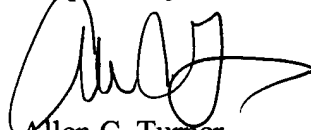
C. 35 U.S.C. § 102:

Claims 1 through 7, 10, 11, 16-18, and 20 stand rejected under 35 U.S.C. § 102 as assertedly being anticipated by U.S. Patent 6,150,500 to Salerno. (Office Action, p. 6). Applicants have amended the claims, and in view of the amendments, request that the rejection be withdrawn.

Specifically, applicants have amended the independent claims to state that the oligopeptides are from Table 6. Basis for the amendments is found throughout the application, but specific basis can be found in canceled claim 9. Salerno does not disclose peptides such as those found in Table 6. Accordingly, the anticipation rejection should be withdrawn.

In view of the foregoing, the application should be in condition for allowance. If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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